## REMARKS

Upon entry of the foregoing amendments, claims 1-5, 7, 62-65 are under consideration.

## I. Claim Rejections-35 U.S.C. § 102(a)

### Dimitroff

Claim 1-5, 7, 62-65 have been rejected under 35 U.S.C. § 102(a) as being unpatenable over Dimitroff. (PNAS 97:13841-13846, 2000); "Dimitroff")

According to the Examiner Dimitroff is prior art under 35 U.S.C. § 102 (a) because the invention was known by "others". Applicants disagree. Dimitroff is not prior art under 35 U.S.C. § 102 (a) as demonstrated by evidence of submitted herewith. Dimitroff was published December 5, 2000 and therefore was not available to the public for more that a year prior to the October 18, 2001 filing date of the instant application.

In *In re Katz* 687 F.2d 450, 215 USPQ 14 (CCPA 1982), the Court held that when a publication occurs less than one year before applicants application, the disclosure comes within the scope of § 102 (a) *only* if the description is not applicants own work. See also MPEP 2132.01. That is not the case here. As discussed above, the December 6, 2000 publication date of Dimitroff is not more than a year prior to the October 18, 2001 filing date the instant application Further, Dimitroff is Applicants' own work -- this is established by evidence of submitted herewith

Applicants submit herewith a Declaration under 1.132 by Robert Sackstein ("Sackstein I Decl.") stating that the current named inventor, Robert Sackstein, solely conceived of the claimed invention. (Sackstein I Decl. ¶ 1). The Declaration further states that Dimitroff, Lee and Fulbrigge, the remaining co-authors on the Dimitroff publication was working under the direct supervision of Dr. Sackstein and did not materially contribute to the conception of the claimed invention. (Sackstein Decl. ¶¶ 4, 5). In *Katz,* the Court held that Dr. Katz's Declaration under 35 U.S.C. § 102(a) stating that the co-authors of the publication who were not named as inventors on the patent application were students working under his direction was a sufficient evidentiary showing to remove the 35 U.S.C. § 102(a) rejection. *Katz* remains good law and applicants here

have made the very same evidentiary showing -- Dr. Sackstein's sworn statement disposes of the basis for the 35 U.S.C. § 102(a) rejection. Applicants request that this rejection be withdrawn.

**Sackstein**

Claim 1-5, 7, 62-65 have been rejected under 35 U.S.C. § 102(b) as being unpatentable over Sackstein. (Blood 89:2773-2781); "Sackstein")

According to the Examiner Sackstein is prior art under 35 U.S.C. § 102 (b) because the hematopoietic cell L-selectin ligand described in Sackstein be the same polypeptide of the claimed invention.

The Examiner asserts that the Sackstein described the isolation of a purified preparation of HCELL/KG1a CD44 protein of the instant invention. In support of his assertion, the Examiner refers to the immunoprecipitation of HCELL/KG1a CD44 as exemplified in Figure 2 and the discussion. Applicants disagree. Figure 2 (or the discussion) does not show immunoprecipitation of HCELL/KG1a CD44. In contrast to the Examiners assertion Figure 2 of Sackstein shows immunoprecipitation from radiolabeleled KG1a cell lysate which demonstrate that MECA-79 reactive polypeptides were not precipitated from KG1a lysates whereas another polypeptide CD43 --not CD44 was precipitated from the KG1a lysates. The other references cited by the Examiner as extrinsic evidence of anticipation- Dimitroff and Sackstein 2 does not change this fact for the reasons discussed herein. Accordingly, Applicants request that this rejection be withdrawn.

**Stamenkovic**

Claim 1-5, 7, 62-65 have been rejected under 35 U.S.C. § 102(b) as being unpatentable over Stamenkovic et al. (EMBO Journal 10:343-348, 1991); "Stamenkovic.")

According to the Examiner Stamenkovic is prior art under 35 U.S.C. § 102 (b) because Stamenkovic teaches the isolation and source of CD44, including immunoprecipitation of CD44 derived form hematopoietic cells. Applicants disagree.

Stamenkovic teaches that there is an epithelial form of the CD44 polypeptide that is distinct from the hematopoietic/mesodermal form. Specifically, Stamenkovic describes that the epithelial form contains an additional extracellular peptide domain interposed proximal to the

membrane-spanning domain and that this additional peptide sequence impairs binding to the extracellular matrix element hyaluronate. Stamenkovic demonstrates these two forms of CD44 by analysis of CD44 transcripts (i.e. RNA) from various cell types. (See Figure 2 in Stamenkovic) Figure 2 is a photograph on an RNA blot and does not indicate that that any CD44 polypeptides were purified from any primary cell line. (Sackstein II. Decl. ¶5).

Stamenkovic does not teach as the Examiner suggests the isolation and source of native CD44 immunoprecipitated from hematopoietic cells. Figure 3 of Stamenkovic demonstrates immunoprecipitation of the "hematopoietic form" of CD44 (CD44H) from CD44H transfected COS cells. The COS cell line is derived from kidney cells of the African Green monkey. CD44H-transfected COS cells cannot produce the claimed glycosylated polypeptide as COS cells are known to lack relevant fucosyltransferases (particularly fucosyltransferase VII), which are essential for producing the sialofucosylated selectin binding determinants of the claimed glycosylated polypeptide. Figure 4 of Stamenkovic demonstrates the immunoprecipitation of CD44 from carcinoma cells (i.e., the epithelial form) not the hematopoietic form. (Sackstein II. Decl. ¶6)

In view of the forgoing, Applicants assert that Stamenkovic does not teach the invention as claimed. The Examiner also cited Sackstein J. Invest. Dermatol. 122:1061-1069, 2004 ("Sackstein 2") as further evidence that the claimed polypeptide is not new or novel. Specifically, Sackstein 2 states:

> Although initially considered to be a novel selectin ligand by the above biochemical criteria, mass spectrometry subsequently revealed that HCELL is not novel *per se*: it is a glycoform of a well-recognized intergral membrane glycoprotein, CD44, that express the CLA epitope (i.e., is recognized by mAb HECA-452).

Applicant asserts that this statement does not mean that that HCELL polypeptide itself was not new, but rather the polypeptide backbone that forms a portion of the claimed polypeptide was known. (Sackstein II. Decl. ¶10)

Applicant requests that this rejection be withdrawn.

## II. Claim Rejections-35 U.S.C. § 103(a)

**Sackstein/Stamenkovic/Ni**

The Examiner has rejected claims 1-4 and 62-65 under 35 U.S.C. § 103(a) over Sackstein and or/and Stamenkovic in view of Ni et al. (US Patent No. 5,952,417 ("Ni")

For the reasons discussed above, neither Sackstein nor Stamenkovic teach the claimed invention. Ni does not cure these deficiencies. Ni merely teaches methods of isolating and expressing isolated protein of interest. Thus, Sackstein or Stamenkovic can not be combined with Ni. According, the rejection should be withdrawn.

## CONCLUSION

Applicants believe that this case is in condition for allowance. If the Examiner has any questions, the Examiner is invited to contact the undersigned by telephone.

Respectfully submitted,

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